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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,803	04/21/2006	Mary J. Champion	D-3150	5915

7590 02/26/2009

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
02/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,803	CHAMPION, MARY J.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33,35,36,38,41,44,45,55,57-59,61-65,68 and 70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,35,36,38,41,44,45,55,57-59,61-65, 68, 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's request for RCE, amendment and declaration, all filed 01/30/2009.

Claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 68, 70 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/30/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 70 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hot flashes by placing cooling device at

location of the upper back of a women who is experiencing hot flashes wherein the location on the upper back being a site of origin of the hot flashes (claims 55, 57-59, 61-65, 68), the specification does not reasonably provide enablement for treating women anticipating hot flashes (claim 70). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention as recited by claim 70 is method for treating hot flashes in women anticipating hot flashes. The entire specification disclosed treatment of hot flashes. Nowhere in the specification applicant disclosed treatment of hot flashes in women anticipating hot flashes. Further, the specification does not enable the treating of the hot flashes in women anticipating hot flashes, i.e. prevention of hot flashes before they occur. The term “treating women anticipating hot flashes” is interpreted by the examiner as "prevention", because

symptoms can not be treated when they are anticipated and before they actually happen and they may or may not occur.

The breadth of the claims: The claim is broad. The claim encompasses treating women anticipating hot flashes in susceptible patients, and the burden of enabling prevention of anticipated hot flashes in susceptible patients would be greater than that of enabling a treatment. This is due to the need of additional testing and screening to those humans anticipating or susceptible to hot flashes. The treatment of hot flashes in women anticipating them before their occurrence may or may not be addressed by the administration of the instant cooling device because not all menopausal women experience hot flashes, which are one of various symptoms of menopausal syndrome.

The state of the prior art: The state of the art recognized treatment of hot flashes using the cooling gelatinous patches (US 2003/0176904 for Patterson). However, the state of the art does not recognize the administration of cooling patches to women anticipating hot flashes to prevent them from happening. The state of the art recognizes the treatment of hot flashes as a symptom of menopausal syndrome, but not its cure or prevention.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The guidance given by the specification on how to treat hot flashes in women anticipating them before they actually happen is absent. Guidance for treatment of hot flashes as a symptom of menopausal syndrome by applying cooling device to the site of onset of the hot flashes is provided, however, no evidence is provided that hot flashes actually have been prevented from

women anticipating hot flashes. Furthermore, the specification provides no guidance, in the way written description, on hot flashes have been prevented in women anticipating them, only treatment of hot flashes as a symptom at the site of its onset. It is not obvious from the disclosure of treatment of a symptom when it arises if its prevention by applying the same cooling device in women anticipating them even before its occurrence will work, simply because it may not occur, and site of its occurrence is not known in order to apply the cooling patch. In the specification, page 17, lines 14-17, applicant disclosed that:

> "While not wishing to be bound by any particular theory or mechanism of action, it has been discovered that placing the cooling device 12 **in an origin site of a hot flash, for example, in a region of the upper back** between the shoulder blades, can substantially reduce at least one symptom of hot flashes associated with menopause, and even substantially alleviate hot flashes associated with menopause. In certain situations, it has been found that placement of a cooling device 12 **at a region in proximity to the cervical and thoracic vertebrae substantially at the onset of a hot flash** or even in anticipation of a hot flash can effectively prevent the hot flash from spreading throughout a woman's body."

Therefore, the disclosure is directed to placing cooling device at the site o onset of the hot flashes, i.e. hot flashes must happens first before treatment by applying the cooling device. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the claimed methods of using fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of significant guidance from the specification or prior art with regard to complete treatment of hot flashes in women anticipating them, which is prevention of hot flashes, makes practicing

the claimed invention unpredictable in terms of the treatment of the hot flashes even before been experienced by women because it is not known who is going to have them.

The presence or absence of working examples: The specification discloses treatment of hot flashes using cooling device. No working examples to show prevention of hot flashes in women anticipating them. Therefore, the specification has enabled only treating hot flashes as a symptom of menopausal syndrome by applying cooling device at the site of origin of the hot flashes and further enabled applying the cooling device at the onset of experiencing the hot flashes, and not treatment of women anticipating them, which is prevention of hot flashes before their occurrence, because they may not occur in all menopausal women.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant method for treating hot flashes in women anticipating them without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Response to Arguments

4. Applicant's arguments filed 01/30/2009 have been fully considered but they are not persuasive.

Applicant argues that the claims as amended overcome the enablement rejection regarding "anticipating hot flashes". However, with careful review of the claims, it is noticed that claim 70 is not amended and the claim still recites the limitation "in

anticipation of hot flashes". The rejection of claim 70 under *35 USC § 112* first paragraph is maintained for reasons of record.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0176904 ('904) for Patterson in view of any of JP 2002119529 ('529) for Kobayashi or US 6,224,899 ('899) for Misumi et al. and further in view of the article "Thermoregulatory physiology of menopausal hot flashes: a review" by Kroneberg et al.

US '904 teaches cooling therapy for women experiencing hot flashes wherein the cooling therapy is provided as bandage comprising strips of cooling gelatinous material, adhesive to fix the gelatinous material to the skin on one side and cotton fabric on the other side (abstract; paragraphs 0010, 0012, claim 4). Cotton is used by applicant as gas permeable substrate at page 13, lines 15-16 of the present specification. The strips can be applied under clothes across the chest (paragraph 0012). The term across, according to the "WEBSTER'S II Dictionary" means: "from one side to the other". Therefore, the disclosure of the reference encompasses the application of the strip or

bandage on the back of the user in order to be under the clothes because the reference is concerned with problem of embarrassing the women using the cooling strips (abstract, paragraph 0008). The reference further teaches that strip is provided in pouch, which reads on the package (paragraph 0012). The reference does not teach the presence of any active agent in the strip. The instruction does not impart patentability of the claims. The claims are obvious by the reference since it has been held by the court that when the only difference between the prior art product and the claim is the "written instruction to the consumer", the claim is obvious over the art. See *In re Ngai 03-1524*.

Although US '904 suggested application of the cooling strip across the chest, however, the reference does not explicitly teach that the back is the site of origin of the hot flashes as recited by claims 33, 55 and 61.

US '904 does not describe the gel as water containing gel comprising polyacrylic acid component as claimed by claims 35, 36, 38, 55, 57-59, 62-65, 67 and 68.

JP '529 teaches cooling patch for cooling the affected regions continuously in early stage and can maintain a cooldown delay, said patch comprises water permeable film covered with hydrous paste of polyacrylic acid, i.e. containing water (abstract; paragraphs 0004-0008).

US '899 teaches adhesive cooling gel contains large amount of water spread on moisture permeable sheet (abstract; col.8, lines 61-66). The adhesive cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue (col.1, lines 53-55, 59-

61). The cooling patch can be applied locally to the area of discomfort without limitation to the body part, such as fever, inflammation, pain or sprain to assuage the discomfort (col.8, lines 41-58).

Kroneberg et al. teach that the onset of the hot flashes and sweating occur primarily on the chest and upper torso, i.e. trunk (page 1313, right column).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a cooling sheet/strip applied across the chest to treat hot flashes comprising gelatinous material located between skin adhesive and cotton fabric layer as disclosed by US '904, and apply the strip to the origin of the hot flashes and make the strip of hydrous material comprising polyacrylic acid as disclosed by any of JP '529 and US '899. One would have been motivated to do so because JP '529 teaches that such a cooling patch can be applied to the affected area that in need of cooling and hydrous polyacrylic acid can maintain the cooling effect while being able to cool the affected part at an early stage and can maintain a cooldown delay. Further, one would have been motivated to do so because US '899 teaches that cooling sheet can be applied locally to the area of discomfort and polyacrylic acid cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue. One would have reasonably expected treating hot flashes using cooling strip or sheet applied across the chest comprising polyacrylic acid gelatinous material located between skin adhesive and cotton fabric layer wherein the strip or sheet is applied at the site of origin of the discomfort, in this case is the hot flash, and is able to maintain the cooling effect and

preserve the coolness to treat hot flashes successfully and effectively. Additionally, one having ordinary skill in the art at the time of the invention would have been motivated to apply the cooling sheet disclosed by the combination of US '904 with any of JP '529 or US '899 to the back of the women as disclosed by Kroneberg et al. One would have been motivated to do so because Kroneberg et al. teach that the onset of the hot flashes and sweating occur primarily on the chest and upper torso. One would have reasonably expected treating hot flashes by applying cooling sheet to the upper back which is the primary site of onset of the hot flashes.

Response to Arguments

7. Applicant's arguments with respect to claims 33, 35, 36, 38, 41, 44, 45, 55, 57-59, 61-65, 68 and 70 have been considered but are moot in view of the new ground(s) of rejection.

Response to Amendment

8. The declaration under 37 CFR 1.132, filed 01/30/2009, is moot in view of the new ground of rejection. "Product Concept Test" is no longer relied upon for rejecting the instant claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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